

Appendix 15:

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From: Jacobson, Elizabeth D.

Subject: RE: A Quick Question

I don't really have a prepared summary, but maybe I can make up a short one:

Yesterday, OSB sponsored a seminar on "Outside Leveraging." Outside leveraging is defined as creating relationships and/or formal agreements with others outside FDA/CDRH to obtain services/support for little or no monetary exchange in order to support our mission.

Purpose of the seminar is for our employees to hear about creative successes and lessons learned by some of the pioneers in outside leveraging, and then apply this knowledge in a follow-up workshop being held today to explore possibilities for outside leveraging.

Speakers who talked about their successes yesterday included outside speakers (obtained with the help of the National Performance Review) from Customs, EPA, and OSHA, and inside speakers from various leveraging projects within CDRH, ORA, and CDER.

Attendees included staff from CDRH, and Office of the Commissioner (OMO, OCC).

The presentations that I heard were excellent, and **very** energizing. It was incredible how closely the problems we face, for example, track with the problems that Customs has. Some of the slides the speaker from Customs used could have been used interchangeably with the slides from our "need to reengineer" talks, and you would never have noticed that they weren't ours.

It was especially helpful to hear from other **regulatory** agencies how they partnered with outside groups, including regulated industry, to get the job done, and yet did not abrogate or weaken their compliance posture with those organizations.

Remains to be seen how much new leveraging activity is generated as a result of the seminar, but it truly was extraordinarily good. It was videotaped, and I heard attendees yesterday asking for copies so they could show it to people back in their offices.

Liz

-----Original Message-----

From: Phillips, Philip J. 594-2022
Subject: A Quick Question

Liz,

I am going to FDA staff this morning. Bruce suggested that I mention the "Outside Leveraging" Workshop that OSB is conducting. He said you have the details. I will try to call you before I leave for Parklawn. On the other hand, if your summary is short you can EMail me. I will check my EMs before leaving. If we do not connect, this will be a topic for next week.

Thanks,

Phil